REMARKS

Claims 13, 15 and 24-27 are pending. Claims 1-12, 14, 16-23 and 28-31 are canceled. Claims 15, 24 and 25 are amended.

Support for the amendment to claim 15 may be found, for example, in the first paragraph of the Summary of Invention bridging pages 1 and 2 of the specification, which teaches therapeutic compositions for increasing antimalignin antibody concentration using SEQ ID NO:1 and/or SEQ ID NO:2.

Support for the amendment to claim 24 may be found, for example, in the first paragraph on page 12 of the specification wherein Applicants disclose SEQ ID NO:1 and SEQ ID NO:2 as epitopes within the aglyco 10B compound. Further support may be found, for example, in Example 8 in the first full paragraph on page 29 of the specification wherein Applicants disclose a kit of claim 24.

Claim 25 is amended to correct a typographical error by adding the article "a" before the phrase "peptide having the amino acid sequence of SEQ ID NO:1 or SEQ ID NO:2." This correction was requested by the Examiner in the pending Office Action.

Objection to the Specification

The Examiner has objected to the priority information in the specification because U.S. Appln. Serial No. 09/817,144 has now issued as Patent No. 6,638,506. Applicants have amended the priority information to reflect that change. Applicants, therefore, respectfully request the Examiner withdraw this objection to the specification.

Objection to the Claim 25

The Examiner has objected to claim 25 because an article is missing before the word "peptide." Applicants have amended the claim to add the article "a" before the word peptide. The Examiner suggested the claim be amended to read "the peptide." Applicants respectfully submit, however, that the article "the" would not be appropriate because "the peptide" would have no antecedent basis and is inappropriate where two different peptides (*i.e.*, SEQ ID NO:1 or

SEQ ID NO:2) are referenced. As such, Applicants have amended the claim to add the article "a," which Applicants respectfully submit responds to the Examiner's objection. In view of Applicants' amendment of claim 25, Applicants respectfully request the Examiner withdraw the objection.

Rejection of Claims 13 and 14—Double Patenting Over 09/854,568

The Examiner has provisionally rejected claims 13 and 14 over claim 6 of U.S. Appln. Ser. No. 09/854,568. Claim 14 is herein canceled and should obviate the rejection of claim 14. Concerning the provisional rejection of claim 13, Applicants respectfully note that claim 6 of U.S. Appln. Ser. No. 09/854,568 is presently withdrawn from that application. Nevertheless, upon a showing by the Examiner that presently pending claim 13 is in condition for allowance and not patentably distinct from issued or allowable claim 6 of U.S. Appln. Ser. No. 09/854,568, Applicants will file a terminal disclaimer pursuant to 37 C.F.R. §§1.130(b) and 1.312.

Rejection of Claims 13 and 14—Double Patenting Over US 4,298,590

The Examiner has rejected claims 13 and 14 over claims 12-14 of US 4,298,590 for double patenting because "claims 12-14 of the '590 patent are directed to an antimalignin antibody with additional limitations" and the antibody of claims 12-14 "would specifically recognize a peptide having the amino acid sequence of SEQ ID NO:2, as in the instant claim 13, or would specifically recognize aglyco protein 10B, as in the instant claim 14." Office Action at 4-5.

Claim 14 has been canceled, which should obviate the rejection of claim 14.

Applicants respectfully traverse the Examiner's rejection of claim 13. Claims 12-14 of US 4,298,590 do not contain a limitation directing the claims to SEQ ID NO:2. Additionally, US 4,298,590 does not identify or disclose SEQ ID NO:2 as an epitope on the malignin protein.

Applicants respectfully submit the Examiner is incorrect to suggest the antibody of claims 12-14 "would specifically recognize a peptide having the amino acid sequence of SEQ ID NO:2." There is no teaching or suggestion in US 4,298,590 that the antibodies described therein bind SEQ ID NO:2. Applicants respectfully submit their understanding that SEQ ID NO:2 was not known in the art before the priority date of the above-captioned application.

Without the teachings of Applicants in the above-captioned application, one of skill in the art would not have known SEQ ID NO:2 might be both antigenic on its own and an epitope on the malignin protein. As such, claims 12-14 of US 4,298,590 could not be used to render claim 13 obvious since they do not teach or suggest SEQ ID NO:2, do not teach or suggest specific epitopes on the malignin protein, and in particular do not teach or suggest SEQ ID NO:2 as an antigenic sequence or an epitope.

In view of the cancellation of claim 14 and the absence of teachings or suggestions of claim 13, Applicants respectfully request the Examiner withdraw the rejection of claims 13 and 14 for double patenting over US 4,298,590.

Rejection of Claim 24—Double Patenting Over US 4,298,590

The Examiner has rejected claim 24 over claims 12-14 of US 4,298,590 in view of US 4,041,146 for double patenting because "[c]laims 12-14 of the '590 patent are directed to an antimalignin antibody with additional limitations." Office Action at 5. Applicants have amended claim 24. The amendment should obviate the double patenting rejection.

Applicants respectfully submit claims 12-14 of US 4,298,590 do not teach or suggest antibodies that bind to SEQ ID NO:1 or SEQ ID NO:2 as claimed. Applicants further submit the claims do not teach or suggest particular epitopes to the claimed anti-malignin antibody and provide no teaching or suggestion that SEQ ID NO:1 or SEQ ID NO:2 are antigenic. Applicants additionally submit their understanding that SEQ ID NO:1 and SEQ ID NO:2 were not known in the art before the priority date of the above-captioned application. As such, one of skill in the art would not find it obvious to even make an antibody to SEQ ID NO:1 or SEQ ID NO:2 and would not find it obvious to use such antibodies to determine the concentration of aglycoprotein 10B antigenic epitopes in the blood of a patient as claimed in claim 24. Because claim 24 would not have been obvious to one of skill in the art over claims 12-14 of US 4,298,590 in view of US 4,041,146, Applicants respectfully request the Examiner withdraw the rejection of claim 24 for double patenting.

Rejection of Claims 13 and 14—Double Patenting Over US 4,486,538

The Examiner has rejected claims 13 and 14 over claims 7-11, 20 and 21 of US 4,486,538 for double patenting because "claims 7-11, 20 and 21 of the '538 patent are directed to a composition comprising a mixture of monoclonal antimalignin antibodies, i.e., antimalignin antibody-fast and slow with additional inherent limitations" and the antibodies of claims 7-11, 20 and 21 of the '538 patent would "specifically recognize a peptide having the amino acid sequence of SEQ ID NO:2." Office Action at 6.

Claim 14 has been canceled. This should obviate the rejection of claim 14.

Applicants respectfully traverse the Examiner's rejection of claim 13. As similarly discussed above with respect to US 4,298,590, the asserted claims of US 4,486,538 do not contain a limitation directing the claims to SEQ ID NO:2. Additionally, US 4,486,538 does not identify or disclose SEQ ID NO:2 as an epitope on the malignin protein.

Applicants respectfully submit the Examiner is incorrect to suggest the antibody of claims 7-11, 20 and 21 "would specifically recognize a peptide having the amino acid sequence of SEQ ID NO:2." There is no teaching or suggestion in US 4,486,538 that the antibodies described therein bind SEQ ID NO:2. Applicants further submit their understanding that SEQ ID NO:2 was not known in the art before the priority date of the above-captioned application. Without the teachings of Applicants in the above-captioned application, one of skill in the art would not have known SEQ ID NO:2 might be both antigenic on its own and an epitope on the malignin protein. As such, the asserted claims of US 4,486,538 could not be used to render claim 13 obvious since they do not teach or suggest SEQ ID NO:2, do not teach or suggest epitopes on the malignin protein, and in particular do not teach or suggest SEQ ID NO:2 as an antigenic sequence or as an epitope on the malignin protein.

In view of the cancellation of claim 14 and the absence of teachings or suggestions of claim 13 in the asserted claims of US 4,486,538, Applicants respectfully request the Examiner withdraw the rejection of claims 13 and 14 for double patenting.

Rejection of Claim 24—Double Patenting Over US 4,486,538

The Examiner has rejected claim 24 over claims 7-11, 20 and 21 of US 4,486,538 in view of US 4,041,146 for double patenting because "[c]laims 7-11, 20 and 21 of the '538 patent are directed to an antimalignin antibody with additional limitations." Office Action at 5. Applicants have amended claim 24. The amendment should obviate the double patenting rejection.

Applicants respectfully submit claims 7-11, 20 and 21 of US 4,486,538 do not teach or suggest antibodies that bind to SEQ ID NO:1 or SEQ ID NO:2 as claimed. Applicants further submit the claims do not teach or suggest particular epitopes to the claimed anti-malignin antibody and provide no teaching or suggestion that SEQ ID NO:1 or SEQ ID NO:2 are antigenic. Applicants additionally submit their understanding that SEQ ID NO:1 and SEQ ID NO:2 were not known in the art before the priority date of the above-captioned application. As such, one of skill in the art would not find it obvious to even make an antibody to SEQ ID NO:1 or SEQ ID NO:2 and would not find it obvious to use such antibodies to determine the concentration of aglycoprotein 10B antigenic epitopes in the blood of a patient as claimed in claim 24. Because claim 24 would not have been obvious to one of skill in the art over claims 7-11, 20 and 21 of US 4,486,538 in view of US 4,041,146, Applicants respectfully request the Examiner withdraw the rejection of claim 24 for double patenting.

Rejection of Claims 15, 25 and 26—Double Patenting Over US 6,242,578

The Examiner has rejected claims 15, 25 and 26 for double patenting over US 6,242,578 (of which the present application is a divisional). The Examiner has rejected claim 15 over claims 4 and 5 of US 6,242,578 and claims 25 and 26 over claims 4 and 5 of US 6,242,578 in view of US 4,041,146. Applicants respectfully point out that claims 4 and 5 of US 6,242,578 and presently pending claims 15, 25 and 26 were subject to a Restriction Requirement in the prosecution of US 6,242,578 on March 15, 2000. Claims 4 and 5 were elected by Applicants as part of restricted Group I. The presently pending claims were not elected and were part of restricted Group IV. As such, the presently pending claims may not be subject to a double patenting rejection over US 6,242,578. *See* 35 U.S.C. § 121. Applicants, therefore, respectfully request the Examiner withdraw this rejection.

Rejection of claim 15—Enablement and Written Description

The Examiner has rejected claim 15 for failure of enablement because "the specification, while being enabling for therapeutic compositions comprising the peptides of SEQ ID NO:1 or 2, does not reasonably provide enablement for therapeutic compositions comprising a peptide of SEQ ID NO:1 or a peptide of SEQ ID NO:2." Office Action at 9. The Examiner has also rejected claim 15 for lack of written description because "the specification fails to provide sufficient descriptive information, such as definitive structural features of each genus of amino acid sequences encompassed by "a peptide of SEQ ID NO:1" or "a peptide of SEQ ID NO:2." Office Action at 13.

Applicants have amended claim 15 to include the terms "the peptide of SEQ ID NO:1" and "the peptide of SEQ ID NO:2." Applicants respectfully submit this amendment responds to the Examiner's rejection. The Examiner has acknowledged that claim 15 is enabled for "therapeutic compositions comprising the peptides of SEQ ID NOs: 1 or 2." Applicants additionally submit claim 15, as amended, is likewise fully described. Because claim 15 as amended is both enabled and described, Applicants respectfully request the Examiner withdraw the rejection of claim 15.

Rejection of claims 13-15 and 27—Anticipation over US 4,486,538

The Examiner has rejected claims 13-15 and 27 for anticipation over US 4,486,538 to Bogoch. The Examiner argues that the US 4,486,538 teaches "monoclonal anti-malignin antibodies that bind to malignin (aglyco protein 10B or a peptide having the amino acid sequence of SEQ ID NO:2 []), thus meeting the limitations of claims 13 and 14." Office Action at 14. The Examiner further asserts US 4,486,538 anticipates claim 15 by "suggest[ing] a therapeutic use" for "antimalignin antibody *in vivo*." *Id.* Finally, the Examiner finds US 4,486,538 anticipates claim 27 because US 4,486,538 "discloses isolating nucleic acids that encode malignin and anti-malignin." *Id.*

Claim 14 has been canceled obviating the rejection of claim 14.

Concerning pending claims 13, 15 and 27, Applicants respectfully traverse the Examiner's rejections and reasoning. Applicants are aware of no teaching or suggestion in US

4,486,538 of anti-malignin antibodies that bind to SEQ ID NO:2, as presently claimed in claim 13, or of a therapeutic composition comprising SEQ ID NO:1 or SEQ ID NO:2, as presently claimed in claim 15. Applicants respectfully submit there is no teaching or suggestion that the anti-malignin antibodies disclosed in US 4,486,538 specifically recognize either of these sequences or that either of these sequences are useful as therapeutic agents to increase antimalignin antibodies, as required by the claims. Applicants additionally submit their understanding that SEQ ID NO:1 and SEQ ID NO:2 were not known in the art before the priority date of the above-captioned application. One of skill in the art could never have guessed or even surmised SEQ ID NO:1 or SEQ ID NO:2 were epitopes of malignin based on the disclosure of US 4,486,538, which apparently contains no information and provides no suggestion of any particular epitopes within the disclosed malignin.

No teaching or suggestion of antibody to SEQ ID NO:2 of claim 13

In view of the absence of a teaching or suggestion in US 4,486,538 of an antibody that specifically recognizes SEQ ID NO:2, Applicants respectfully submit the Examiner misstates the teaching of US 4,486,538 when the Examiner asserts US 4,486,538 teaches monoclononal anti-malignin antibodies that bind to "a peptide having the amino acid sequence of SEQ ID NO:2." *Id.* at 14. Malignin is disclosed in US 4,486,538 as composed of *approximately* 88 amino acids. Col. 15, line 13. The sequence of the protein is not disclosed. Not even the actual length of the protein is disclosed. No epitopes within the protein are discussed; no antibody is characterized as specifically binding SEQ ID NO:2; SEQ ID NO:2 is not disclosed as antigenic; and there is apparently no teaching or suggestion by which a researcher might even "try" to create an antibody to SEQ ID NO:2. As such, no antibody to SEQ ID NO:2 is disclosed. Applicants, therefore, respectfully request the Examiner reconsider the assertion that US 4,486,538 teaches antibodies that bind SEQ ID NO:2 and withdraw the rejection of claim 13.

No teaching or suggestion of therapeutic use of claim 15

Further, Applicants respectfully submit US 4,486,538 does not teach or suggest a therapeutic composition comprising SEQ ID NO:1 or SEQ ID NO:2 (or a combination thereof) as claimed in amended claim 15. The Examiner suggests the patent teaches that "aglycoprotein 10B (malignin) causes production of antimalignin antibody in vivo and suggests a therapeutic

use for raising said production in cancer patients." Office Action at 14. Claim 15, as amended, should obviate the Examiner's reasons for the rejection. As discussed above, US 4,486,538 does not teach or suggest the peptides of SEQ ID NO:1 or SEQ ID NO:2 or antibodies to SEQ ID NO:1 or SEQ ID NO:2 and does not teach or suggest therapeutic use of these peptides. Example 6 of the above-captioned application provides extensive discussion of differences between the anti-malignin antibodies such as those disclosed in US 4,486,538 and antibodies of the present invention. *See* Specification at 22. Because the peptides and their therapeutic use referenced in claim 15 are not disclosed or suggested in US 4,486,538, Applicants respectfully request the Examiner withdraw the rejection of claim 15.

No teaching or suggestion of SEQ ID NO:1 or SEQ ID NO:2 of claim 27

Applicants additionally request the Examiner reconsider the assertion that US 4,486,538 anticipates claim 27 by disclosing nucleic acids that encode malignin, including SEQ ID NO:1 and SEQ ID NO:2. Office Action at 14. Applicants respectfully assert that disclosing *approximate* numbers of particular amino acid residues within a protein and providing an *approximate* total number of amino acid residues based on those approximations (with no disclosure of sequence information) does not constitute a teaching suggesting "isolating nucleic acids that encode malignin" to one of skill in the art. *See* US 4,486,538 col. 14, line 60, through col. 15, line 23. To the contrary, Applicants respectfully submit US 4,486,538 provides no teaching or suggestion concerning SEQ ID NO:1 or SEQ ID NO:2 and no teaching or suggestion concerning an isolated nucleic acid encoding a peptide comprising the amino acid sequence of SEQ ID NO:1 or SEQ ID NO:2. As discussed above, one of skill in the art could not have conceived of SEQ ID NO:1 or SEQ ID NO:2 from the disclosure of US 4,486,538 since no epitopes of malignin are discussed and no sequence information is provided. As such, Applicants respectfully request the Examiner withdraw this rejection.

Rejection of claim 15—Anticipation over US 4,298,590

The Examiner has rejected claim 15 for anticipation over US 4,298,590 to Bogoch because US 4,298,590 "teaches that malignin (aglycoprotein 10B) causes production of antimalignin antibody and teaches that the antibody is useful as a therapeutic in treating cancer." Office Action at 15. Applicants respectfully submit the amendment to claim 15 obviates this

rejection. As discussed above, US 4,298,590 does not teach or suggest the claimed therapeutic composition of claim 15 since it does not teach that SEQ ID NO:1 or SEQ ID NO:2 are antigenic and does not teach that these sequences are epitopes on the malignin protein. Applicants additionally submit their understanding that SEQ ID NO:1 and SEQ ID NO:2 were not known in the art before the priority date of the above-captioned application. As such, US 4,298,590 does not teach or suggest a therapeutic composition for increasing antimalignin antibody concentration comprising a peptide selected from the group consisting of SEQ ID NO:1 or SEQ ID NO:2.

Because US 4,298,590 does not teach or suggest claim 15 as amended, Applicants respectfully request the Examiner withdraw the rejection.

Rejection of claim 15—Anticipation over Weston

The Examiner has rejected claim 15 for anticipation over Weston *et al.* (J. Mol. Biol. 1986 Nov 20; 192(2);177-208) because Weston teaches "peptides that comprise 3 adjacent amino acids of Applicants' SEQ ID NO:1." Applicants respectfully submit claim 15 as amended is not anticipated by Weston because Weston does not teach or suggest a therapeutic composition comprising a peptide selected from the group consisting of the peptide of SEQ ID NO:1 or the peptide of SEQ ID NO:2. Applicants respectfully request the Examiner withdraw the rejection of claim 15.

Rejection of claim 15—Anticipation over Lui

The Examiner has rejected claim 15 for anticipation over Lui *et al.* (Cell 1989 Apr 21;57(2):233-42) because Lui teaches "peptides that comprise 4 adjacent amino acids of Applicants' SEQ ID NO:2." Applicants respectfully submit claim 15 as amended is not anticipated by Lui because Lui does not teach or suggest a therapeutic composition comprising a peptide selected from the group consisting of the peptide of SEQ ID NO:1 or the peptide of SEQ ID NO:2. Applicants respectfully request the Examiner withdraw the rejection of claim 15.

Rejection of claims 13-15 and 24-27—Obviousness over US 4,486,538

The Examiner has rejected claims 13-15 and 24-27 for obviousness over US 4,486,538 to Bogoch in view of US 4,041,146 to Giaever. The Examiner argues that the US 4,486,538

teaches "monoclonal anti-malignin antibodies that bind to malignin (aglyco protein 10B or a peptide having the amino acid sequence of SEQ ID NO:2 []) as in claims 13 and 14." Office Action at 18. The Examiner further asserts US 4,486,538 renders claim 15 obvious by suggesting "a therapeutic use" for "antimalignin antibody in vivo." *Id.* The Examiner also argues US 4,486,538 in view of US 4,041,146 renders claims 24-26 obvious by suggesting coating a tube with antigenic material or antibodies. Finally, the Examiner alleges claim 27 is obvious over US 4,486,538 because, the Examiner alleges, the patent "discloses isolating nucleic acids that encode malignin (a peptide comprising SEQ ID NO:1 or SEQ ID NO:2) and anti-malignin."

Claim 14 has been canceled obviating the rejection of claim 14.

Concerning pending claims 13, 15 and 24-27, Applicants respectfully traverse the Examiner's rejections and reasoning. As discussed above, Applicants are aware of no teaching or suggestion in US 4,486,538 of anti-malignin antibodies that bind to SEQ ID NO:1 or SEQ ID NO:2, as presently claimed in claim 13 and 15. In fact, Applicants submit SEQ ID NO:1 and SEQ ID NO:2 are not disclosed in US 4,486,538 and there is no teaching or suggestion that the anti-malignin antibodies disclosed therein "specifically" recognize either sequence or that those sequences are individually antigenic or epitopes on the disclosed malignin protein. Applicants additionally submit their understanding that SEQ ID NO:1 and SEQ ID NO:2 were not known in the art before the priority date of the above-captioned application. One of skill in the art could never have guessed or even surmised SEQ ID NO:1 or SEQ ID NO:2 were epitopes of malignin to which antibodies could be directed.

No teaching or suggestion of SEQ ID NO:1 or SEQ ID NO:2 as claimed in claims 13, 15 or 27

In view of the absence of a teaching or suggestion in US 4,486,538 of an antibody that specifically recognizes SEQ ID NO:2, Applicants respectfully request the Examiner withdraw the rejection of claim 13. Additionally, because antibodies to SEQ ID NO:1 and SEQ ID NO:2 are not disclosed or suggested in US 4,486,538, Applicants respectfully request the Examiner withdraw the rejection of claim 15. Likewise, because US 4,486,538 apparently does not disclose SEQ ID NO:1 or SEQ ID NO:2, does not provide actual sequence information for the disclosed malignin protein, and does not suggest where the skilled artisan might find epitopes on

the malignin protein, Applicants respectfully request the Examiner withdraw the rejection of claim 27.

No teaching or suggestion of claims 24-26

The Examiner argues US 4,486,538 in view of US 4,041,146 renders claims 24-26 obvious by teaching coating a tube with antigenic materials or antibodies. Claims 24 to 26 are directed to the use of SEQ ID NO:1 and SEQ ID NO:2. US 4,486,538 does not teach or suggest SEQ ID NO:1 or SEQ ID NO:2 because the patent does not disclose or suggest a sequence for malignin, does not disclose or suggest specific epitopes of malignin and certainly does not disclose or suggest SEQ ID NO:1 or SEQ ID NO:2. In the absence of such a teaching, one of skill in the art could never have arrived at the use of SEQ ID NO:1 or SEQ ID NO:2 in a kit for detecting anti-malignin antibody or the use of antibodies to SEQ ID NO:1 or SEQ ID NO:2. As such, Applicants respectfully submit claims 24-26 are not obvious over US 4,486,538 in view of US 4,041,146 and request the Examiner withdraw this rejection.

CONCLUSION

Applicants respectfully submit the claims are now in condition for allowance and earnestly solicit an early and favorable action on the merits. The Commissioner is authorized to charge any fees required in connection with this matter, to Kenyon & Kenyon LLP **Deposit Account No. 11-0600**.

The Examiner is invited to contact the undersigned to discuss any issues related to this application.

Respectfully submitted,

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